Cancel claim 38.

New Claim

Claim 39 (new). A method for inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment which comprises feeding the pet an antioxidant or mixture of antioxidants at levels sufficient to accomplish the said inhibiting or increasing, the said antioxidant selected from the group consisting Vitamin E, Vitamin C, alpha lipoic acid, I-carnitine and mixtures thereof.

Remarks

Claims 1-37 remain in the case. Claim 38 is cancelled. Claim 39 is newly added.

The objections to the claims and rejection under 35 USC 112 have been overcome by the amendments in all cases but the following.

With respect to claims 2-5 and 24-25, it is noted that a "companion pet' as noted in claim 1 from which 2-5 depend therefrom includes more than canine and felines. Certainly gerbils, hamsters, ferrets, and the like could also be considered companion pets. Still further, the nutrition requirements, diets, of canines and felines do differ. A feline requires substantially more meat, generally, than a canine, also see USP 6,203,825. Therefore, the dietary requirements do differ.

Claims 1 and 37 can differ significantly. The quantity of antioxidant therein is defined by the functional limitation of the claim. In claim 1, the amount is "to inhibit the deterioration of the mental capacity" of the pet while in claim 37, the amount is to "increase metal capacity of the pet. Claim 1 stops or slows

down the deterioration of the mental capacity while claim 37 actually <u>increases</u> mental capacity from where it is. These are not "intended use" limitations as stated in the Office Action but real limitations on the <u>amounts</u> of antioxidant present. The claims are certainly of different scope.

The art rejections of the claims are under 35USC 102, anticipation, and 35USC 103, obviousness are now considered.

Claims 1-5 and 37 are rejected under Bernotavicz.

This reference discloses no specific diet which would anticipate any of these claims. Rather, there are only combinations of unknown vitamins and minerals at unknown percent, for example wherein 1, lines 54-60 disclose

"1 to 7 percent supplemental ingredients <u>like</u> vitamins, minerals, flavoring, coloring, antioxidants and <u>other</u> ingredients" (emphasis supplied),

At column 5, lines 25-44 there is no indication what materials can be present; 25 to 100% of daily requirements is a huge range. There is nothing to indicate that there is enough "vitamins", "antioxidants" and the like to equal the amounts required in claims 1 and 37. It is respectfully submitted that anticipation is absent.

Claims 1-5, 8 and 37 are rejected as anticipated over Paluch. This reference is directed to a dual component (core shell) pet food. The Office Action refers to three passages of Paluch. Column 4, lines 61-63 refers to the diet being nutritionally complete according to AFCO standard. This passage does not disclose there are sufficient antioxidant amounts to accomplish the functions of claim 1 or 37. Column 6, lines 7-11 also does not disclose any quantities of antioxidants. Column 8, lines 28-31 only refers to the size,

dimensions, of the animal food product, not to its composition. Novelty of the rejected claims is still present.

Claims 1-8, 12, 13, 15, 19, 26, 27, 29, 33 and 37 were rejected under 35USC102 for being anticipated over Harper. This is an extremely lengthy reference, 56 pages of specification and 4 pages of figures. One paragraph is related to the rejected claims. At page 13, Vitamin E and other aspects of the Harper invention is "for use in the prevention or treatment of any disorder which has a component of oxidation stress." The "use is separately for the prevention or treatment of oxidative stress as a component of a disease or 'disorder'. . . "

After this, 12 different diseases or disorders are named including "aging." In no claims, particularly new claim 39, is there any reference to an amount - composition claims - or a method of preventing or treating a disease or the oxidative stress as a component of the disease. Rather, the claims refer to deterioration of "mental capacity" or specifically to learning capacity. There is no focus in Harper nor any reference to this effect. Moreover, the breadth and vagueness of the Harper disclosure is insufficient to support a novelty rejection, much less an obviousness rejection.

Milgram (abstract) was used to reject claims 1, 2, 12, 13, 26, 27 and 37. No specific antioxidant is provided in the abstract. Furthermore, one of the authors is the same S. Zicker as the inventors in the patent application. Further evidence can be brought forth, if necessary, to obviate this abstract use for either novelty or obviousness.

Claims 6, 7, 9-11 and 12-36 are rejected for obviousness over Bernotavicz and Paluch in view of Sole et al and Weischer et al. It should be noted that claims 1-5 and 8 are not rejected anywhere for obviousness. The first two references have already been discussed. They are, if anything, notable for their vagueness and as to what <u>may</u> be present in their formulations. Sole

and Weischer used in combination with the first two references are alleged in the Office Action to make obvious the claimed invention. Various portions of each reference are noted for their disclosures in the Office Action. Sole is directed to the use of a food <u>supplement</u> to bring about certain therapeutic effects. Column 12, lines 45-50 discloses that

"The ability to withstand peroxidative injury is <u>partially</u> dependent on diet" (emphasis supplied). It goes on to say that a "good dietary intake of the antioxidant Vitamins C and E and trace nutrient materials such as selenium with adequate cysteine as a precursor for glutathione synthesis are important for protection against free radical injury".

The disclosure refers to <u>normal dietary intake</u>, not to a supplement that is prepared with <u>enhanced</u> levels of materials. With respect to increased levels of free radical, all the reference says at column 4, lines 27-33 is that with respect to such increased levels "the pathogenesis of various neurodegenerative diseases is gaining increased acceptance." This is not a ringing endorsement of the role of free radicals and their inhibition as <u>positive motivation</u>, a requirement of obviousness as opposed to "obvious to try." The projected treatment of this disorder is carnitine in combination with coenzyme Q-10 and taurine - only one of which is positively claimed in this application. The use of Vitamin E and C are not necessary. Alpha-lipoic acid is never mentioned. Although a disorder such as a neurogenerative disease is mentioned, among many, see column 15, lines 40-46, there is no specific mention of any <u>specific</u> neurogenerative disease, how it manifests itself, or how the treatment affects the disease.

Weischer discloses a cocktail of alpha-lipoic acid and at least one vitamin for improved medication for at least thirteen (13) separate conditions - one of which is "neuroprotective" - whatever that means. No further disclosure on

neuroprotection seems to be made. When providing doses for the various conditions at column 11, lines 8-15 mentioned in the Office Action, neuroprotective diseases are notable by their absence.

Neither Weischer nor Sole together provide adequate disclosure to support a rejection for obviousness, particularly for the directed method of use claims. The conclusions drawn from the combination of references presented in the Office Action are unsupported by the actual reference disclosures.

Claims 8, 9-11, 14, 16, 17, 18, 20-25, 28, 30-32 and 34-36 are rejected for obviousness under Harper in view of Sole and Packer. Harper has been discussed previously. Its vagueness and indefiniteness makes it a poor candidate for a primary reference in a combination obviousness rejection. Sole has also been previously commented upon with its weaknesses being noted. Packer is used as a second secondary reference replacing Weischer in the prior combination obviousness rejection. The Packer reference is a broad almost treatise like reference on alpha lipoic acid. Neurodegenerative diseases as observed is an incredibly broad almost shot gun like disclosure on these materials. The mere fact that alpha lipoic acid might bring about improved memory performance in aged mice at a very high dosage is not demonstrative evidence in establishing the strong likelihood that it will have a cognitive effect in dogs and cats, particularly that of the method of use claim 39, directed toward learning capabilities which is significantly different than memory loss. Additionally, man, monkey, mice, and rats are substantially different than dogs and cats.

The rejection for double patenting and double patenting in an obviousness sense are noted. When agreement is reached on the merits, such rejection will be fully addressed (parent application) and a terminal disclaimer filed if necessary.

Related applications to this one include the following:

| 6562-01 | USSN 9/922,660 | Filed August 6, 2001 |
|---------|----------------|------------------------|
| 6562-02 | USSN 9/978,132 | Filed October 16, 2001 |
| 6564-01 | USSN 9/922,633 | Filed August 6, 2001 |

Applicants by their attorney respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

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